



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stoll

Examiner: W. Jarvis

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Title: OMEGA-3 FATTY ACIDS AND OMEGA-3 PHOSPHATIDYL-CHOLINE IN THE TREATMENT OF BIPOLAR DISORDER

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

DECLARATION UNDER 37 C.F.R. 1.132

I, Lauren B. Marangell, M.D., declare:

1. I received my medical doctor degree from Baylor College of Medicine in 1987.
2. I was an intern, resident, and chief resident at Albert Einstein College of Medicine/Montefiore Medical Center between 1987 and 1991, and a fellow and senior staff fellow at the National Institute of Mental Health, Biological Psychiatry Branch, between 1991 and 1994.
3. During my residency and fellowship, I received the Albert Einstein College/Mead Johnson Award, the National Institute of Mental Health Outstanding Resident Award, and the Laughlin Fellowship of the American College of Psychiatrists.
4. I joined the faculty of Baylor College of Medicine in July 1994. I am currently the Director of Clinical Psychopharmacology, Director of Mood Disorders Research, and Assistant Professor of Psychiatry at the Baylor College of Medicine.

A Speech

5. I am an author of a number of articles relating to pharmaceutical treatment of bipolar disorder. A list of some of these articles is attached as an appendix.

6. As a result of my general background, knowledge, and experience with mood disorders, I offer the following statements and opinions:

A. Bipolar disorder is a neuropsychiatric disorder with distinct phases of illness. A patient may exhibit symptoms of mania, major depression, or both simultaneously (mixed manic states). Patients may also go through periods of remission during which they do not exhibit abnormal mood symptoms.

B. Manic depressive psychosis is understood as an extreme manifestation of a manic phase marked by hallucinations or delusions indicating a break with reality. Not all patients with bipolar disorder will experience manic depressive psychosis.


C. Drugs that alleviate a depressive phase in a patient with bipolar disorder may not alleviate symptoms of a manic or mixed manic phase. Indeed, some such drugs, *e.g.*, anti-depressants, will even exacerbate manic or mixed manic symptoms. Likewise, drugs that effectively relieve manic symptoms may be ineffective during a depressive phase or a mixed manic phase.

D. That a composition is effective at relieving certain symptoms associated with one manifestation of bipolar disorder does not suggest that the composition will effectively relieve or prevent other phases of bipolar disorder. For example, it does not immediately follow that a composition for treatment of manic depressive psychosis will effectively treat or prevent a depressive or mixed manic phase as well.

7. All statements made herein are of my own knowledge are true and all statements made on information are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Lauren B. Marangell, M.D.

Dated: 8/28/01_____

Appendix

Post RM, Ketter TA, Pazzaglia PJ, George MS, Marangell L, Denicoff K. New developments in the use of anticonvulsants as mood stabilizers. *Neuropsychobiology*, 1993; 27: 132-137

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